#### NOTICE OF INTENT

#### Department of Health Board of Medical Examiners

Physician Practice; Marijuana for Therapeutic Use by Patients Suffering From a Debilitating Medical Condition (LAC 46:XLV.Chapter 77)

Editor's Note: This Notice of Intent is being repromulgated to correct processing errors. The original Notice of Intent may be viewed on pages 1872-1874 of the December 20, 2019 edition of the *Louisiana Register*.

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 et. seq., and pursuant to the authority vested in the Louisiana State Board of Medical Examiners (board) by the Louisiana Medical Practice Act, R.S. 37:1270, and Louisiana law governing medical marijuana, R.S. 40:1046, the Board intends to amend its Rules governing physicians who diagnose their patients with a debilitating medical condition for which marijuana may be recommended, LAC 46:XLV Chapter 77. The proposed amendments are needed to conform the board's rules to Act 284 of the 2019 Regular Session of the Louisiana Legislature. Among other items, the proposed changes remove the: (i) provision requiring annual reporting by the board to the legislature as to its views on any additional diseases or conditions that should be added to the list of debilitating conditions (§7701.A.2); (ii) definition of step therapy or fail first protocols (§7705.A), as well as the corollary exceptions respecting such use (§7709.A.2); and (iii) physician domiciliary requirement for a physician to recommend marijuana (§7711.A.3). The proposed amendments also modify the definition of marijuana to exclude a metereddose inhaler, if permitted by rules adopted by the Louisiana Board of Pharmacy, from the general prohibition against inhalation as an acceptable form of medical marijuana (§7705.A).

#### Title 46

# PROFESSIONAL AND OCCUPATIONAL STANDARDS Part XLV. Medical Professions Subpart 3. Practice

Chapter 77. Marijuana for Therapeutic Use by Patients Suffering from a Debilitating Condition

Subchapter A. General Provisions

#### §7701. Preamble, Warning, and Suggested Consultation

A. Preamble—State Law. Pursuant to Act 261, R.S. 40:1046, of the 2015 Session of the Louisiana Legislature, as amended and supplemented by Act 96 of the 2016 Session of the Louisiana Legislature, the Louisiana State Board of Medical Examiners was directed to:

1. ...

2. Repealed.

B. - C. ...

AUTHORITY NOTE:Promulgated in accordance with R.S. 37:1261-1292 and R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2631 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:318 (February 2017), LR 46:

#### §7705. Definitions

A. As used in this Chapter, the following terms and phrases shall have the meanings specified.

\* \* \*

Marijuana—tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols in any form, except for inhalation, raw or crude marijuana, as permitted by the rules and regulations of the Louisiana Board of Pharmacy (LBP). For purposes of this definition *inhalation* shall not exclude a form of medical marijuana administered by metered-dose inhaler to the extent permitted by LBP rules.

\* \* \*

Step Therapy or Fail First Protocols—repealed.

\* \* \*

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:319 (February 2017), LR 46:

### Subchapter B. Prohibitions and Exceptions §7709. Exceptions

A. This Chapter is subject to the following exceptions.

1. ..

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:319 (February 2017), LR 46:

#### Subchapter C. Registration

#### §7711. Registration, Physician Eligibility

A. To be eligible for registration under this Chapter a physician shall, as of the date of the application:

1. - 2. ...

3. Repealed.

A.4. - D....

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015), amended by the Department of Health, Board of Medical Examiners LR 43:319 (February 2017), LR 46:

#### **Family Impact Statement**

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed amendments on the family has been considered. It is not anticipated that the proposed amendments will have any impact on family, formation, stability or autonomy, as described in R.S. 49:972.

#### **Poverty Statement**

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed amendments on those that may be living at or below one hundred percent of the federal poverty line has been considered. It is not anticipated that the proposed amendments will have any impact on child, individual or family poverty in relation to individual or community asset development, as described in R.S. 49:973.

#### **Provider Statement**

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed amendments on organizations that provide services for individuals with developmental disabilities has been considered. It is not anticipated that the proposed amendments will have any impact on the staffing, costs or overall ability of such organizations to provide the same level of services, as described in HCR 170.

#### **Small Business Analysis**

It is not anticipated that the proposed amendments will have any adverse impact on small businesses as defined in the Regulatory Flexibility Act, R.S. 49:965.2 et seq.

#### **Public Comments**

Interested persons may submit written data, views, arguments, information or comments on the proposed amendments to Rita Arceneaux, Confidential Executive Assistant, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until January 20, 2020.

#### **Public Hearing**

A request pursuant to R.S. 49:953(A)(2) for a public hearing must be made in writing and received by the Board within 20 days of the date of this notice. If a public hearing is requested to provide data, views, arguments, information or comments orally in accordance with the Louisiana Administrative Procedure Act, the hearing will be held on January 27, 2020 at 9 a.m., at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130. Any person wishing to attend should call to confirm that a hearing is being held.

Vincent A. Culotta, Jr., M.D., Executive Director

### FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

#### RULE TITLE: Physician Practice; Marijuana for Therapeutic Use by Patients Suffering From a Debilitating Medical Condition

### I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule changes will result in a one-time publication expense estimated to total \$639 in FY 20 for the LA State Board of Medical Examiners (LSBME). Otherwise, it is not anticipated that the proposed changes will have any impact on any state or local governmental units, inclusive of adjustments in workload and paperwork requirements.

The proposed rule changes amend rules governing the practice of physicians who diagnose their patients with a qualifying debilitating medical condition (DMC) for which therapeutic marijuana (TM) may be recommended to conform them to Act 284 of 2019. Consistent with Act 284, the proposed changes amend the Board's existing rules to remove the following requirements: for annual reporting by the Board to the legislature as to any additional diseases or conditions that should be added/removed from the list of DMCs; that a physician utilize step therapy or fail first protocols and the exceptions respecting its use; and that a physician be domiciled and practice at a physical practice location in this state to recommend TM. Lastly, the proposed changes modify the definition of marijuana to exclude a metered-dose inhaler, as permitted by rules adopted by the Board of Pharmacy, from the general prohibition against "inhalation" as an acceptable form of TM

### II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule changes will not affect revenue collections for state or local governmental units.

## III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

It is not anticipated that the proposed rule changes will significantly affect the workload and/or income of physicians who may diagnose or patients who may be treated with TM for a debilitating medical condition. Patients who may be recommended TM for a DMC may benefit, as the proposed rule changes ease access to TM.

### IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes are not anticipated to affect competition and employment.

Vincent A. Culotta, Jr. M.D. Executive Director 2001#072 Evan Brasseaux Staff Director Legislative Fiscal Office